

**REMARKS/ARGUMENTS**

Claims 1-23, 26, 28, 29 and 31 are pending in the instant application. Claims 1 and 5 have been amended to more particularly point out and distinctly claim that which Applicants consider to be their invention. Claims 7, 22 and 23 have been cancelled without prejudice.

Upon entry of the above-made amendments, therefore, claims 1-6, 8-21, 26, 28, 29 and 31 will be pending in the current application. The amended claims are fully supported in the specification as originally filed. Therefore, the amendments to the claims do not add new matter. Applicants respectively request that the amendments be entered.

The following remarks, in conjunction with the above amendments, are believed to be fully responsive to the Office Action.

**THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

**SHOULD BE WITHDRAWN**

In the application, claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. In particular, the Examiner has objected to the use of "I" in the formula as confusing. In response, Applicants submit that claim 5 has been amended as suggested by the Examiner. Therefore the rejection should be withdrawn.

For all the above reasons, Applicants respectfully submit that each of the Examiner's rejections under 35 U.S.C. § 112, second paragraph has been overcome and/or obviated. Applicants therefore respectfully request that the rejections be withdrawn.

**THE REJECTION UNDER 35 U.S.C. § 102**

**SHOULD BE WITHDRAWN**

Claims 1-23, 26, 28, 29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Tomalia, US Patent No. 5,714,166 ("Tomalia"). In response, Applicants submit that each of the rejections should be withdrawn for the reasons stated below.

As noted above, claim 1 has been amended to introduce the limitations of "a targeting agent capable of traveling to or binding specifically to targeted cells, tissues, organs or other location in a mammalian body" and "said targeting agent comprises E. coli heat stable enterotoxin STa".

A finding of anticipation under 35 U.S.C. § 102 requires the disclosure in a single prior art reference of each element of the claim under consideration. *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Found. v. Genetech Inc.*, 927 F.2d 1565, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991).

Applicant respectfully submit that Claim 1, as amended to include the limitation "a targeting agent capable of traveling to or binding specifically to targeted cells, tissues, organs or other locations in a mammalian body" and the further limitation that "said targeting agent

comprises E. coli heat stable enterotoxin STa" is fully distinguishable from Tomalia.

Support for these amendments is found at pages 11, lines 23-33 and 14, lines 10-12 respectively. Tomalia does not disclose, teach or suggest compounds as defined in the instant claim 1. STARBURST<sup>TM</sup> conjugates which contain a targeting director are described in Tomalia column 22, line 15 to column 25, line 4. Tomalia further describes targeting directors as antibodies, monoclonal antibodies and fragments of antibodies, hormones, biological response modifiers and epitopes. The targeting agent of the present application comprises E. coli heat stable enterotoxin STa which is not in any way revealed by Tomalia. As Tomalia fails to disclose, teach or suggest compounds comprising E. coli heat stable enterotoxin STa, Applicants respectfully submit that the present invention is not anticipated by Tomalia.

Thus, Applicants respectfully submit that each of the Examiner's rejections under 35 U.S.C. 102 has been overcome and/or obviated and respectfully request that the rejections be withdrawn.

**THE REJECTION UNDER 35 U.S.C. § 103(a) SHOULD BE WITHDRAWN**

Claims 1-23, 26, 28, 29 and 31 are rejected under 35 U.S.C. 102(e) as being unpatentable over Tomalia. In response, Applicants submit that each of the rejections should be withdrawn for the reasons stated below.

As stated above, claim 1 has been amended to introduce the limitations of “a targeting agent capable of traveling to or binding specifically to targeted cells, tissues, organs or other location in a mammalian body” and “said targeting agent comprises E. coli heat stable enterotoxin STa”. There is no teaching or suggestion in Tomalia of compounds comprising E. coli heat stable enterotoxin STa. In view of the above, Tomalia does not in any way teach or suggest the claimed invention in the instant application.

Thus, Applicants respectfully submit that each of the Examiner’s rejections under 35 U.S.C. 103 has been overcome and/or obviated and respectfully request that the rejections be withdrawn.

### **CONCLUSION**

In view of the amendments and remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner’s rejections and objections, and allowance of the current application are respectfully requested.

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The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Respectfully submitted,



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